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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,799	01/16/2004	Richard Derosc	05500-00128-US1	6502
23416	7590	09/28/2005	EXAMINER	
CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899			IBRAHIM, MEDINA AHMED	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,799

Applicant(s)

DEROSE ET AL.

Examiner

Medina A. Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/16/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 35-65 are pending and are examined.

Claim Objections

At claim 55, "an" in line 2 should be changed to ---the--- because it refers to a previous claim.

At claim 59, "a" should be changed to ---the--- because it refers to a previous claim.

At claim 60, "a" should be changed to ---the--- because it refers to a previous claim.

At claim 61, "a" should be changed to ---the--- in each occurrence, because it refers to a previous claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 is indefinite because "capable" implies that the reference sequence may or may not function in monocots. The specification fails to describe the conditions under which the sequence may or may not function in monocots. Dependent claims 42-49 are included in the rejection.

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Claim 44 is indefinite because the groups listed are DNA sequences rather than proteins. Appropriate correction is required to more clearly define the metes and bounds of the claims.

At claims 52 and 54, the designations "OTP/double-mutant EPSP" and "OTP/CP4" are unclear, and are not defined in the specification.

At claim 57, "the expression vector" lacks antecedent basis because claim 41 is drawn to a expression cassette rather than an expression vector.

Claim Rejections - 35 USC § 112, Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA construct comprising the isolated maize H3C4 promoter (SEQ ID NO: 1), combined with the first intron of rice actin (SEQ ID NO: 2) or SEQ ID NO: 3 regulating the expression of a heterologous protein in plant cells, and a method for using said DNA construct to transform plants/plant cells, does not reasonably provide enablement for DNA sequence comprising a functional fragment of the maize H3C4 promoter and a functional fragment of the first intron of rice actin or homologous sequences of the disclosed sequences allowing the expression of heterologous proteins in transformed plants/plant cells/seeds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

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nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a DNA sequence comprising a functional fragment of any size of the sequence of the maize H3C4 promoter and a functional fragment of any size of the sequence of the first intron of rice actin, sequences homologous to the disclosed sequences allowing the expression of heterologous proteins in monocot plants or plant cells for a desired agronomic property. The claims are also drawn to methods for controlling weed and culturing transformed plants by using a functional fragment of the maize H3C4 promoter and a functional fragment of the first intron of rice actin, or sequences homologous to SEQ ID NO: 1, 2, and 3 and retaining the respective regulatory activity.

Applicant provides guidance for an expression cassette comprising SEQ ID NO: 3 or the full-length sequence of the maize H3C4 promoter (SEQ ID NO: 1) combined with full-length sequence of the first intron of rice actin (SEQ ID NO: 2), regulating the expression of heterologous proteins in maize plants and plant cells. Applicant also provided guidance for a method of conferring herbicide tolerance in maize plants and plant cells by expressing heterologous proteins that confer herbicide tolerance under the control of unmodified maize H3C4 promoter or SEQ ID NO: 1 combined with unmodified first intron of rice actin or SEQ ID NO: 2 or SEQ ID NO: 3 (see Figures 1-3).

Applicant has not provided guidance for a functional fragment of the maize H3C4 promoter and a functional fragment the first intron of rice actin that retains respective regulatory activity. No guidance has been provided for any modifications of SEQ ID NO:

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1, 2, or 3 that resulted homologous sequences that retain promoter, enhancer or any other regulatory activity. The specification does not provide guidance regarding the identification, isolation, or evaluation of fragments or homologous sequences of the maize H3C4 promoter or the first intron of rice actin or for their ability to drive heterologous gene expression in exemplified or non-exemplified monocot cells. Furthermore, homologous sequences are defined in the specification as modified sequences having at least 70%-90% homology to SEQ ID NO: 1, 2, and 3. However, Applicant has not provided guidance as to what modifications would allow the disclosed sequences to retain their respective regulatory activity; so as heterologous genes can be expressed to provide a desired agronomic trait, especially herbicide tolerance in monocot plants. No region necessary for regulatory activity has been disclosed or evaluated. In addition, the working examples disclosed in the specification are limited to the use of unmodified SEQ ID NO: 1 and 2 or 3. Therefore, it is unclear as to whether one skilled in the art would be able to use the claimed "functional fragments or homologous sequences to control and enhance gene expression, especially herbicide resistance genes in transgenic plants, without undue experimentation.

The state of the art teaches unpredictability inherent in promoter function and tissue-specificity when one or more nucleotide bases of the promoter are modified. For example, Kim et al (Plant Molecular Biology, 1994 vol. 24, pp. 105-117) teach the extreme sensitivity of promoter regions to single base pair changes, the absolute requirement for as few as 3 to 6 nucleotides for promoter function, and the failure of a promoter to function either constitutively or specifically when lacking oligonucleotide

regions approximately 100 bp upstream of the transcription start site (page 106, paragraph bridging the columns; paragraph bridging pages 107 and 108; page 110, paragraph bridging the columns).

Benfey et al (Science, 1990, vol. 250, pages 959-966) teach tissue specificity of fragments of the CaMV 35S promoter can vary depending on the location of the fragment within a promoter (Figure 1, page 960). Therefore, the ability of the claimed fragment and homologous sequences to function as promoter/intron is uncertain. In addition, the claimed homologous sequences having at least 70% sequence identity would comprise non- functional transcriptional, translational, and enhancer elements, i.e. modifications to highly conserved promoter regions such as CAAT, TATA, and intron-specific elements, known in the prior art, required for proper expression of genes, may be rendered inactive by said modifications. While Applicant is not required to exemplify each and every claimed embodiment, specific guidance is required with respect to which regions of the disclosed sequences can be modified so that the respective regulatory activity is retained. Absent such guidance, one skilled in the art would have to make all possible combinations of fragments of the maize H3C4 promoter with fragments of the rice actin1 intron, and test which combined fragments would provide the desired level of gene expression when introduced into transgenic plants. These tests are considered undue.

Therefore, given the lack of guidance as discussed supra; the unpredictability inherent in the function of a promoter and an intron when lacking specific regions

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necessary for regulatory activity, the breadth of the claims; and state of the art, the claimed invention is not enabled throughout the broad scope.

See *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991), where it is taught that the disclosure of a single gene sequence did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 35-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention does not meet the current written description requirement for the following reasons: Firstly, Applicant has not described a single variant of the disclosed sequences having the structural and functional properties as recited in the claims. Secondly, Applicant only described SEQ ID NO: 3 and a method of using it. Applicant fails to describe the composition and structure of other nucleic acid sequences encompassed by the claims. In particular, Applicant has not described functional fragments of the maize H3C4 promoter, functional fragments of the first intron of rice actin, and homologous sequences of the disclosed sequences having regulatory activity. Consequently, Applicant fails to provide an adequate written description for expression vectors, plants, plant cells and seed comprising said sequences, and for methods for using said sequences to express a desired gene in a monocot plant.

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See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), where the court stated that to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of members of the genus". See, also Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-65 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,750,378. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both the application and the issued patent are drawn to a DNA sequence comprising the maize H3C4 promoter and the rice actin intron operably linked to a DNA encoding a protein of interest, an expression vector/cassette comprising said sequences and a method of transforming plants and plant cells with

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said DNA sequences for a desired agronomic trait. The two inventions relate as species/genus. The invention claimed in the application, drawn to a DNA sequence comprising a functional fragment of any size of the sequence of the maize H3C4 promoter and a functional fragment of any size of the sequence of the first intron of rice actin, sequences homologous to the disclosed sequences allowing the expression of heterologous proteins in monocot plants or plant cells for a desired agronomic property, and methods for transforming plant/plant cells with said functional fragments, or homologous sequences of SEQ ID NO: 1, 2, and 3 and retaining the respective regulatory activity are broader in scope than the invention claimed in the issued patent, which is a DNA sequence comprising SEQ ID NO: 1 and 2 or 3, and methods of transforming plant and plant cells with said DNA sequences. Therefore, the invention claimed in the application and therefore fully encompasses the invention claimed in the issued patent. Therefore, the claimed invention is obvious over the invention claimed in the issued patent.

Remarks

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/19/05

Mai

MEDINA A. IBRAHIM
PATENT EXAMINER

A handwritten signature in black ink, appearing to read 'Medina A. Ibrahim', is written over the printed name and title.